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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,871	02/23/2004	Malcolm King	11157-74	7085

1059 7590 02/26/2007

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,871	KING, MALCOLM	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/3/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-9, 11, 12, 14-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 1, 2, 4, 6-10, 14, 15, 17, 19 of U. S. Patent No. 6,339,075 in view of Speert et al. (5,514,665).

Claims 1-3, 6-9, 11, 12, 14-17 of the instant application teaches a method of decreasing viscoelasticity of respiratory tract mucus, a method of treatment for improving respiratory tract mucus clearance in an animal associated with a lung disease (listed in claim 9) comprising administering an effective amount of low molecular weight (500-5000) charged dextran to the respiratory tract mucus.

The patent (U.S. 6,339,075) discloses a method of improving mucus clearance comprising administering to the respiratory tract of a patient associated with a lung disease such as cystic fibrosis (listed in claim 8) an effective amount of dextran (molecular weight 360-4000). The patent does not teach charged dextran in a method of decreasing viscoelasticity of respiratory tract mucus.

Speert et al. teaches a method of administering a composition comprising dextran or dextran sulfate to cystic fibrosis (CF) patients to reduce the risk of infection by bacterial pathogens (col. 5, lines 14-20). The reference further teaches that by the method of administering dextran or dextran sulfate reduces the risk of or prevents the establishment of infection of the respiratory system by bacterial pathogens (col. 3 lines 30-45).

It would have been obvious to one of ordinary skill in the art to administer dextran sulfate for dextran in U.S. 6,339,075 to decrease viscoelasticity of respiratory tract mucus. The motivation to do is taught by Speert et al. The reference teaches the interchangeability of using dextran or dextran sulfate in a method for reducing the risk or preventing infections by bacterial pathogens in vivo in cystic fibrosis patients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1--9, 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al (Am J.Respir Crit Care Med, Vol. 157, p 710-714) in view of Speert et al. (5,514,665).

Feng et al. teaches that dextran significantly reduced viscoelasticity and increased mucocilary and cough clearability in Cystic Fibrosis patients' sputum and in

healthy dog mucus (see Abstract). The reference teaches invitro studies of collecting mucus samples of dogs to test the rheologic properties (viscoelasticity) and mucocilary and cough clearability by adding different concentrations of dextran (0.4%, 4.0%) to the samples (see Abstract, p 711, Methods). The reference teaches measuring of viscoelasticity and clearance indices (p 711, col.2 lines 19-28) and indicates that dextran (0.4%, 4.0%) significantly decreased the viscoelasticity and mucocilary clearability only increased significantly for 4% dextran. Though the reference does not explicitly teach the 'invitro studies' as 'diagnostic study' it would have been obvious to one of ordinary skill in the art to use the in vitro study model in a method of diagnosis in an animal with impaired mucus clearance because the reference teaches every step of claims 19 and 20, obtaining the sample of the animal's mucus, treating in vitro with dextran with different concentrations, determining the effect of dextran on the viscoelasticity for each sample, and determining the preferred dosage of dextran based on the effects of dextran on the viscoelasticity.

The reference does not teach a method of administering dextran sulfate to an animal to decrease the viscoelasticity of respiratory tract mucus nor treating an animal that does not have a detectable bacterial infection.

Speert et al. teaches a method of administering a composition comprising dextran or dextran sulfate in a diluent or a pharmaceutically acceptable carrier, to cystic fibrosis (CF) patients to reduce the risk of infection by bacterial pathogens (col. 5, lines 14-20). The reference specifically teaches that dextran or dextran sulfate will be effective in reducing the risk of or preventing bacterial pathogens infections in

compromised hosts (such as patients with CF) (col. 5, lines 14-20). The reference teaches a method for reducing the risk of or preventing the establishment of infection of the respiratory system by bacterial pathogens by treating individuals with a composition comprising dextran or dextran sulfate (col. 3, lines 30-45). Hence the population includes a subset that has not been infected but is at risk of getting infected by bacterial pathogens and this meets the limitation of 'an animal that does not have a detectable bacterial infection' in claim 1 of the instant application. The reference teaches that excessive viscid mucus causes obstruction of passageways including pancreatic and bile ducts, the intestines, and bronchi in cystic fibrosis patients (col. 1, lines 61-63). The reference teaches that dextran sulfate as the active ingredient may be administered topically by gargle, swish and swallow, oral lozenge, aerosol (inhalation) (col. 6, lines 49-51). A dosage of 10-20mmol of dextran sulfate is disclosed, wherein 20mmol is 160mg/ml of dextran sulfate in solution (col. 6, lines 36-37). The reference teaches that the molecular weight of dextran sulfate may range from 2000 and 10000 (col. 3, lines 56-57).

It is obvious that the composition comprising dextran sulfate is administered to mucus because a) Speert et al. teaches administering composition comprising dextran sulfate to Cystic Fibrosis patients, and Webster's Dictionary defines Cystic Fibrosis as 'a common hereditary disease especially among whites that appears usually in early childhood, involves functional disorder of the exocrine glands, and is marked especially by faulty digestion due to a deficiency of pancreatic enzymes, by difficulty in breathing due to ***mucus accumulation in airways***, and by excessive loss of salt in the sweat'; b)

administration of an aerosol composition, via inhalation, is directly administered to the respiratory tract; thus, one of skill in the art would have anticipated the method of Speert et al. as administering a dextran sulfate composition to the mucus because Cystic Fibrosis patients have mucus in their airways and aerosol inhalation administers active agents to the respiratory tract.

It would have been obvious to one of ordinary skill in the art to administer dextran sulfate for dextran to decrease viscoelasticity of respiratory tract mucus. The motivation to do is taught by Speert et al. The reference teaches the interchangeability of using dextran or dextran sulfate in a method for reducing the risk or preventing infections by bacterial pathogens in vivo in cystic fibrosis patients.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al (Am J.Respir Crit Care Med, Vol. 157, p 710-714) in view of Speert et al. (5,514,665) as applied to claims 1--9, 11-20 and further in view of Brown (U.S. 5,741,527).

Feng and Speert et al. do not teach the animal as a horse with heaves in a method of decreasing viscoelasticity of respiratory tract mucus.

Brown teaches heaves as a respiratory disorder (col.4, lines 59-65).

It would have been obvious to one of ordinary skill in the art to administer dextran sulfate to an animal such as horse for the treatment of heaves. The motivation is to do so is provided by Brown and Feng. Brown teaches heaves to be a respiratory disorder and Speert et al and Feng teaches the decrease in viscoelasticity of CF sputum in vitro by the administration of dextran and Speert teaches the administration of dextran sulfate to CF patients and it is known that CF is a respiratory disorder. Hence it would

have been obvious to one of ordinary skill in the art to administer a drug such as dextran sulfate for the treatment of heaves in horse as both heaves and cystic fibrosis are respiratory disorders.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.